Robert & Mary Gadbois 358 Boston Post Rd. East Lyme, Conn. 06333 April 13, 1999

Dockets Management Branch (HFA- 305), Food & Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, Md. 20852

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To Whom It May Concern:

We are submitting the following comments for Docket No. 99N-0386 and respectfully request they be considered when the entire record of written and verbal comments are reviewed.

The public can be educated about the concept of balancing risks against benefits as a part of the decision making process very simply. When veterinarians prescribe any medication for our pets (in our case for our three Siberians) we --- their owners --- can be given the package inserts and/or computer printouts of those medications before being given the medications. After reviewing that material we will then be in a position of being able to intelligently discuss that medication with the vet, to be able to intelligently ask questions of the vet, and to decide based on accurate and complete information whether or not we want our pet to take that medication. We will be informed clients, and the patients ---- our pets ---- will have the benefit of a process that allows us their owners to weigh the risks against the benefits together with the vet.

When one of our Siberians was given Rimadyl a year ago we were never given the opportunity to do that. We were given the Rimadyl, told it was safe, and nothing more. Even when she experienced immediate side-effects we were kept in the dark. Only later, and not from the vet who gave that Rimadyl, did we discover our pet was experiencing side-effects. This ended up causing her a lot of health problems, cost us a lot of money, and put her through tons of medical tests. Had we been given the package insert and/or a computer print-out for Rimadyl we quite possibly would have decided to not give Rimadyl to her. At the very least, we certainly would have been aware of the side-effects, could have taken her off the Rimadyl immediately rather than keep her on a drug causing her to be sick, and would have been aware of what this drug was all about. Instead, we were totally ignorant.... and not be choice, we must add. We are still dealing with the resulting problems even today.

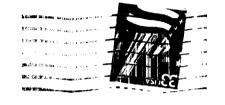
When people get prescriptions filled they always receive a printout of some type with their prescription. They are educated consumers. Why can't this be done for our pets? The FDA should most definitely work to get a procedure in place for this. The FDA should require drug manufacturers to require that this information always be provided along with the drugs each time a vet prescribes medication. Our pets will only benefit when risk and benefits are equally presented.

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